NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO McNEIL PHARMACEUTICAL, INC., et al., Plaintiffs,	x	Civil Action No. 03-4678 (SRC)
v.	x	**OPINION**
BARR LABORATORIES, INC., Defendant.	x	

CHESLER, U.S.D.J.

This matter comes before the Court on the motion by Plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho") for a preliminary injunction, pursuant to FED. R. CIV. P. 65, enjoining Defendant Barr Laboratories, Inc. ("Barr") from marketing or selling a generic version of the oral contraceptive Ortho Tri-Cyclen Lo ("TCL"). For the reasons stated below, Ortho's motion for a preliminary injunction is **GRANTED**.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. On April 10, 2001, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,214,815 (the "'815 patent"). Ortho owns the '815 patent. The claims of the '815 patent cover the combination oral contraceptive that Ortho markets under the name "Ortho Tri-Cyclen Lo."

In July of 2003, Barr filed an Abbreviated New Drug Application ("ANDA"), No. 76-784, with the United States Food and Drug Administration, seeking approval to market a generic

version of Ortho Tri-Cyclen Lo prior to the expiration of the '815 patent. On August 20, 2003, Barr notified Ortho of its certification that the '815 patent is invalid due to anticipation and obviousness. On October 1, 2003, Ortho initiated the instant action by filing a Complaint for infringement of claims 1 and 4 of the '815 patent. As affirmative defenses to patent infringement, Barr contends that these claims are invalid as anticipated and obvious in view of the prior art, including two patents: U.S. Patent No. 4,616,006 (the "'006 patent") and U.S. Patent No. 4,628,051 (the "'051 patent") (collectively referred to as the "Pasquale patents.")

On June 29, 2009, Barr received approval from the Food & Drug Administration to market a generic version of TCL, and there is no dispute that it has shipped some of the product to distributors. On July 1, 2009, Ortho filed the instant application for a preliminary injunction. The parties fully briefed the application and, on July 15, 2009, this Court heard oral argument.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008).

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

[T]he patentee seeking a preliminary injunction in a patent infringement suit must

> show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation omitted).

"[A]n issued patent comes with a statutory presumption of validity under 35 U.S.C. § 282." Id.

> If [] the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument. . . .
>
> [T]he trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings. Then . . . if the trial court concludes there is a 'substantial question' concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.

Id. at 1377-79.

The Federal Circuit then stated definitively the standard that the trial court must apply in ruling on a validity challenge in the context of an application for preliminary injunction:

> [W]hen analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.

Id. at 1379.

II. Patent Invalidity

The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. "This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (quotation omitted).

A. Invalidity due to Anticipation

A patent may be invalidated for anticipation under 35 U.S.C. § 102, which states:

> A person shall be entitled to a patent unless . . .
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

"To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation." Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1334 (Fed. Cir. 2008). "Anticipation is a question of fact. However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law." SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005).

B. Invalidity due to obviousness

To patent an invention, the subject matter must be non-obvious:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

The Federal Circuit has set forth these basic principles to guide the determination of obviousness:

> Obviousness is ultimately a question of law, based on underlying factual determinations. The factual determinations that form the basis of the legal conclusion of obviousness include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, known as objective indicia of non-obviousness.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1007 (Fed. Cir. 2009) (citations omitted).

ANALYSIS

I. Plaintiff has demonstrated that Ortho is likely to succeed on the merits.

On August 3, 2005, this Court entered a consent Order granting partial summary judgment of infringement to Ortho on claims 1 and 4 of the '815 patent. Barr's defenses to infringement, asserting patent invalidity, remain to be tried. Thus, at this juncture, Ortho's likelihood of success on the merits turns on the question of the validity of the '815 patent.

Barr contends that the '815 patent is invalid because: 1) it is anticipated by the earlier '006 and '051 patents; and 2) it is obvious. On October 23, 2006, this Court denied two motions for summary judgment on patent invalidity due to anticipation and obviousness.

A. Invalidity due to anticipation

In the summary judgment Opinion, this Court stated:

> The parties do not dispute that, except for the estrogen dosage limitation, every limitation of claims 1 and 4 of the '815 patent is found expressly in the specification of both of the prior art patents. Example 4 in both the '006 and '051 patents contains the 7/7/7 regimen with the same progestogen dosages and phasing as appears in claims 1 and 4 of the '815 patent. Although Example 4 does not describe the use of 7 dosage units free of estrogen and progestogen, those limitations are found in the specification of both patents (e.g., '006 Patent, col. 3 ll. 42-49.) There is no dispute that the only limitation in claims 1 and 4 of the '815 patent *not* in the prior art Example 4 (read in conjunction with the remainder of the specification) is the 25 microgram dose of ethinyl estradiol ("EE") (since

> Example 4 discloses a 35 microgram dose of EE).
>
> The prior art patents do, however, disclose "contraceptively effective dosages corresponding in activity to 0.02 - 0.05 mg of" EE.[1] ('006 Patent, col. 8 ll. 9-11; '051 Patent, col. 7 ll. 21-23). The core of the dispute over anticipation is the question of whether the prior art disclosure of the range of 20 to 50 micrograms of EE describes the 25 microgram EE dosage limitation, within the meaning of 35 U.S.C. § 102.
>
> There is no substantial dispute over the relevant legal standard, although each party phrases it differently. Ortho phrases the question as whether one of ordinary skill in the art would have "at once envisaged" the 25 microgram dosage after having reviewed the prior art, while Barr states the question as whether the prior art described the 25 microgram dosage to one of ordinary skill in the art, such that it would have been "immediately apparent." (Pls.' § 102 Br. 2; Def.'s § 102 Opp. Br. 22-23.) Ortho states that the "immediately apparent" formulation does not differ from the "at once envisaged" standard. (Pls.' § 102 Reply Br. 6 n.5.) Barr does not contend that the differences in phrasing have any legal significance for the purposes of this motion. Each wording attempts to express the § 102(b) requirement that the invention be "described."

(Opinion of October 23, 2006 at 6-7.)

In its opposition brief, Barr argues that the Pasquale patents "describe the '815 regimen," thus anticipating claims 1 and 4, but does not reference the "immediately apparent" or "at once envisaged" standard. (Def.'s Opp. Br. 11.) Barr's support for its position comes entirely from the expert report of Dr. James A. Simon, who stated that "it would have been apparent to the person of ordinary skill in the art that the description of the 20 - 50 µg in the '006 patent described the use of 7 particular EE dosages . . . including a constant dosage of 25 µg of EE." (Johnson Dec. Ex. 5 ¶ 24; see also ¶ 34.) Ortho points to contrary statements by its experts, Drs. Philip Darney and Rogerio Lobo. (Sonnenschein Dec. Ex. OO ¶ 77, Ex. F ¶ 79.)

The parties do not dispute the fact that the 20 - 50 µg range in the '006 patent describes

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[1] This is equal to a range of 20 - 50 micrograms of EE.

some very large number of possible dosage regimens. Barr's opposition brief does not address the question of whether one of ordinary skill in the art would have at once envisaged the TCL regimen, amidst that large number of possible regimens, or whether the TCL regimen would have been immediately apparent.

Ultimately, however, the decision on anticipation turns on the factual question of whether the Pasquale patents would have described claims 1 and 4 to the person of ordinary skill in the art. At trial, this will be resolved by a battle of the experts. At this juncture, not having heard the experts testify and undergo cross-examination, and not having had the opportunity to weigh their credibility, this Court can find no reason to credit one expert over another. Certainly Barr gives no reason to credit its expert over Ortho's. This Court finds no basis to conclude that it is more likely than not that Barr will be able to prove, by clear and convincing evidence, that the Pasquale patents anticipated claims 1 and 4.

Moreover, this Court takes note of the fact that the Pasquale patents were before the examiner during prosecution of the '815 patent. The Federal Circuit has held that the burden of establishing invalidity is "especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo, 376 F.3d at 1348. Especially in view of this difficulty, then, from the present record, it does not appear more likely than not that Barr will be able to prove anticipation by clear and convincing evidence at trial.

B. Invalidity due to obviousness

As to invalidity due to obviousness, in Iron Grip, the Federal Circuit held:

> [W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness. But the presumption will be rebutted if it can be shown: (1) That the prior art taught away from the

> claimed invention; or (2) that there are new and unexpected results relative to the prior art.

392 F.3d at 1322 (citations omitted). There is no dispute that there is a range disclosed in the prior art, and that the claimed invention falls within that range; there is therefore a presumption of obviousness. At issue is whether Ortho will be able to prove at trial that either the prior art taught away from the invention or that there are unexpected results.

To make its case for obviousness, Barr relies on these propositions: 1) as of 1998, the art had been moving toward reducing estrogen dosages in oral contraceptive ("OC") formulations; 2) the art in 1998 did not teach away from lower EE doses; and 3) in 1998, a person of ordinary skill in the art would have expected that lower EE doses would not lead to more cycle control problems. In the evidentiary record presently before this Court, as discussed above in regard to the issue of anticipation, the Court finds principally a battle of experts as well as references that were before the examiner during prosecution.

On the subject of the state of the art in 1998, however, this Court has found one piece of evidence more deserving of weight than others. Ortho offered an article published in the spring of 1998 by Dr. Philip Darney and Ms. Cynthia Klaisle that surveyed menstrual problems associated with various contraception methods. (Sonnenschein Dec. Ex. L.) The article was published in "Dialogues in Contraception," sponsored by the University of Southern California School of Medicine. (Id.) This article states: "As estrogen doses decline, cycle control decreases. OCs containing 20 mcg estrogen have been found to have higher rates of breakthrough bleeding and spotting than do formulations containing 30 or 35 mcg of estrogen." (Id. at 2.) The article cites the Ackerlund reference and states:

> In another randomized study comparing OCs containing 150 mcg of desogestrel and either 30 or 20 mcg of ethinyl estradiol, the incidence of breakthrough bleeding or spotting was significantly higher with the 150/20 formulation than with the 150/30 formulation.

(Id.)

This Court gives the article by Darney and Klaisle significant weight. It has the hallmarks of being an impartial scientific assessment of the state of the art in 1998, the year the application for the '815 patent was filed. It provides significant evidence that the art at that time taught away from the claimed invention, and supports finding that the cycle control characteristics associated with the lower dose of EE in TCL were an unexpected result. Furthermore, it provides impartial and thus credible support for the position that the Ackerlund study taught that formulations which reduced EE to 20 mcg were associated with a significantly higher rate of breakthrough bleeding – thus teaching away from the claimed invention.

Barr contends that, in 1998, the art "taught that multiple regimens using EE dosages below 30 μg were acceptable and had cycle control that was not meaningfully different from higher dose regimens." (Def.'s Opp. Br. 15.) This proposition – central to Barr's invalidity case – is not supported by the 1998 Darney and Klaisle article. Barr supports its case primarily by pointing to the rebuttal expert report of Dr. James A. Simon. (Johnson Dec. Ex. 7.) Dr. Simon states: "The person of ordinary skill at the end of 1998 would not have expected Tri-Cyclen Lo would be associated with a substantial loss of cycle control as compared to Tri-Cyclen." (Id. at ¶ 32.) Yet Barr itself makes an assertion which undercuts this point: "The art was moving towards lower doses of EE in spite of the potential for additional bleeding." (Def.'s Opp. Br. 15.) This contention concedes one of Ortho's main points: the use of "in spite of" points to the unstated,

underlying assertion that the art believed that lower estrogen doses carried some potential for increased bleeding. This is consistent with the position taken by Darney and Klaisle in their article.

Barr also argues that, in formulating TCL, the applicant merely reduced the EE dosage of Tri-Cyclen which, following KSR, was the obvious use of a known technique to modify a known device. This argument is unpersuasive for several reasons. First, it cuts far too broadly: one can use this argument to show that all dosage reductions are obvious, which seems unlikely to be true. Furthermore, KSR states: "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007). Ortho's main point is that the dosage reduction did not affect the medication in the same way as other reductions had – by leading to increased breakthrough bleeding – but in a different and unexpected way. Careful examination of KSR, applied to the evidence presently of record, shows that the case is actually quite helpful to Ortho.

In KSR, the Supreme Court revisited the obviousness analysis, addressing the exact issues which arise in this case. Id. The Court reaffirmed the approach it had stated a half-century earlier in Graham, where it explained that the obviousness determination

> lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought

> to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17-18 (1966). Unexpected results fall into the category of secondary considerations which *may* have relevancy as indicia of nonobviousness.

In reaffirming Graham, the KSR Court stated: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." 550 U.S. at 416. Thus, while unexpected results are a secondary consideration, in cases in which the patentee has combined familiar elements according to known methods, the predictable or unexpected nature of the results obtained may be especially informative. The Court then discussed how this principle operated in three prior cases. As to Adams, the Court stated: "The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art." Id. As to Anderson, the Court stated that the two pre-existing elements "in combination did no more than they would in separate, sequential operation," and that the combination of them "added nothing." Id. at 417. As to Sakraida, the Court stated that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." Id. (quoting Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976)). In each of these three cases, then, the Court looked to the question of whether the combination of old elements produced expected or unexpected results as an important indicator of obviousness.

In the instant case, there appears to be no dispute that the '815 patent claims an

improvement over the prior art, and that the innovation involves the combination of pre-existing elements. At issue is the question of whether unexpected results lead to a legal conclusion of patent validity under § 103. This legal determination rests on the determination of two underlying factual questions: 1) the nature of the results the invention actually achieved over the prior art; and 2) whether one of ordinary skill in the art would have expected such results from the combination at that time.

Barr contends that "Ortho's unexpected properties argument must fail as a legal matter because its evidence does not show unexpectedly superior properties versus the closest prior art." (Def.'s Opp. Br. 19.) As evidence, Barr points only to the expert report of Dr. Darney, in which the expert reviewed another expert's report and stated: "even for those few cycles in which there is are [sic] *statistically* significant differences in the unscheduled bleeding experienced with ORTHO TRI-CYCLEN and ORTHO TRI-CYCLEN LO . . ., the differences do not, by and large, appear to be *clinically* significant." (Johnson Dec. Ex. 14 ¶ 100.) Barr here appears to miss the point. This Court understands Dr. Darney to have said that the data showed that the TCL formulation was able to achieve a side-effect profile similar to the formulation that used a higher EE dose even though it used a lower EE dose. The unexpected and useful result was the achievement of a side-effect profile that was not worse, as would have been expected, but similar to that obtained with the less desirable higher dose. It is the similar side-effect profile in the context of a lower EE dosage that is the unexpectedly superior property. Dr. Darney's expert report supports this conclusion. It does not support Barr's position.

Barr next argues that Ortho's argument fails because, "to be legally cognizable, an unexpected property must represent a difference in kind from the prior art, not just a difference in

degree." (Def.'s Opp. Br. 20.) This position suffers from a big problem: it relies on two pre-KSR cases. In KSR, the Supreme Court began by rejecting the "rigid approach" of the Federal Circuit to the obviousness analysis and proceeded to hold that the law required a flexible approach, particularly with regard to the role of predictable results in the analysis. 550 U.S. at 415. Thus, without reaching Barr's characterizations of what these two pre-KSR cases held, this Court doubts that any such categorical approach to the obviousness analysis survived KSR.

Barr then states that, "[a]s a factual matter, the cycle control provided by Tri-Cyclen Lo is not unexpected." (Def.'s Opp. Br. 20.) In support, Barr offers the rebuttal expert report of Dr. James Simon. (Johnson Dec. Ex. 7.) Dr. Simon examined the research related to the question of the cycle control properties of TCL. (Id. at ¶¶ 21-38.) He concludes that TCL provided acceptable cycle control, which one of ordinary skill in the art would have expected in 1998. (Id. at 32.)

In response, Ortho argues that: 1) the Patent Office thought otherwise; and 2) leaders in the field viewed TLC's cycle control as unexpected. (Pl.'s Reply Br. 10.) As to the first point, Ortho offered the file wrapper for the '815 patent. (Sonnenschein Dec. Ex. KK.) In the office action of May 24, 2000, the Examiner stated that the applicant's submissions were "persuasive as to the nonobviousness and allowability of the invention of claims 14 and 26 since they demonstrate unexpected cycle control for the inventive 25 µg EE/norgestimate COC unit." (5/24/2000 Office Action at 2.) Barr has not disputed that the applicant overcame an obviousness rejection during the application process.

The Court finds this quite significant and weighs it heavily. The available evidence supports Ortho's position that the PTO considered the question of whether the TCL formulation

provided unexpected cycle control and was ultimately persuaded that the formulation was nonobvious and patentable because of the unexpected results. In addition, the Court notes that the Tuimala, Ackerlund, and Endrikat references cited at oral argument by Barr were before the PTO during prosecution. ('815 Patent, "References Cited: Other Publications;" Barr's Hrg. Presentation Slide 19.) The fact that the applicant overcame an obviousness rejection and convinced the PTO that unexpected results supported the conclusion that the invention was patentably nonobvious weighs strongly in favor of finding that Ortho has demonstrated a likelihood of success on the merits of patent validity.

In support of its contention that leaders in the field found TCL's cycle control to be unexpected, Ortho offers the expert report of Dr. Philip Darney. (Sonnenschein Dec. Ex. OO ¶ 99.) As with the issue of anticipation, the parties are setting up a factual dispute that will likely be resolved by a battle of the experts. At this point, both sides have experts supporting their respective positions. As discussed, not having heard the experts testify and undergo cross-examination, and not having had the opportunity to weigh their credibility, this Court can find no reason to credit one expert over another. Barr gives no reason to credit its expert over Ortho's. This Court gives much more weight to the facts related to the prosecution of the '815 patent, and the 1998 Darney and Klaisle article. This evidence weighs strongly in favor of finding that the patent is nonobvious and valid. This Court cannot conclude that it is more likely than not that Barr will be able to prove at trial, by clear and convincing evidence, that the patent is invalid due to obviousness.

The parties also raise the matter of TCL's commercial success, one of the secondary indicia of obviousness. Barr argues that the prior art Pasquale patents blocked competitors from

entering the marketplace, and that, therefore, any inference of nonobviousness based on TCL's commercial success is weak. This Court agrees and gives the evidence of TCL's commercial success little weight in the obviousness inquiry.

As discussed above, pursuant to Iron Grip, because the claimed invention falls within a range disclosed in the prior art, this raises a presumption of obviousness. At this juncture, Ortho is likely to succeed on defending the validity of its patent if it is likely to rebut the presumption of obviousness. In view of the evidence of record, and particularly in view of the fact that the applicant overcame an obviousness challenge based on many of the cited prior art references during prosecution, this Court cannot conclude that it is more likely than not that Barr will be able to prove at trial, by clear and convincing evidence, that the patent is invalid. This Court therefore finds that Ortho is likely to succeed in defending the validity of its patent at trial and, because infringement has already been determined, Ortho has demonstrated that it is likely to succeed on the merits.

II. Plaintiff has demonstrated that it is likely to suffer irreparable harm in the absence of preliminary relief.

The parties dispute whether the presumption of irreparable harm survived the Supreme Court's Ebay decision. Although, as this Court discussed at the preliminary injunction hearing, the Court is of the view that the presumption of irreparable harm, Pfizer, Inc. v. Teva Pharms.USA, Inc., 429 F.3d 1364, 1381 (Fed. Cir. 2005), did not survive the Supreme Court's decision in Ebay, resolving this legal question is unnecessary for deciding the instant motion. Ortho has demonstrated that it is likely to suffer irreparable harm in the absence of preliminary relief.

In support of its position, Ortho offers the declaration of Katherine Capperella, Senior Director of Global New Business Development for Johnson & Johnson Pharmaceutical Services. Ms. Capperella stated that, since its introduction in 2002, TCL had generated approximately $1.6 billion in profits for Ortho. (Sonnenschein Dec. Ex. A ¶ 3.) Ortho predicts net TCL sales of $162 million for the period of July through December of 2009, assuming that no generic competitor enters the marketplace. (Id. at ¶ 4.) Ms. Capparella estimated that, based on historical comparisons, entry of a generic competitor would produce an 80% drop in net sales of TCL in the first twelve months. (Id. at ¶ 6.) Entry of a generic competitor would lead to irreversible erosion of TCL's market price, since managed care providers are unlikely to agree to resume paying pre-generic prices for a product after a generic version has become available. (Id. at ¶ 11.)

In rebuttal, Barr offers the declaration of an expert, economist Roy Weinstein. Mr. Weinstein stated that the economic impact on Ortho from Barr's entry into the marketplace is readily calculable. (Weinstein Dec. ¶ 7.) He reasoned that, as TCL sales are tracked, and present levels are known, any change due to generic competition would be readily and accurately measured. (Id. at ¶¶ 18-22.) Yet, one paragraph later, Mr. Weinstein argues that the most recent sales data shows that TCL sales and market share have been decreasing. (Id. at ¶ 23.) Barr cannot have it both ways: if future sales prospects for TCL are dynamic and uncertain, any damages calculation based on assuming a constant level of sales is unreliable.

In reply, Ortho offers the declaration of an expert, economist Marion B. Steward. (Sonnenschein Dec. Ex. XX.) Dr. Steward states that entry into the marketplace of a generic competitor would result in cutbacks to research and development, which will produce economic

consequences that cannot be quantified. (Id. at ¶¶ 9, 12.) Dr. Steward points out as well that, were Barr to enter its product into the marketplace, and then lose at trial, the damages calculation would almost certainly involve an estimate of future damages, which would necessarily be subject to considerable uncertainty. (Id. at ¶ 14.)

Having heard the evidence offered by the parties, this Court finds that Ortho has demonstrated that it is likely to suffer irreparable harm in the absence of a grant of injunctive relief. Not granting the injunction will cause Ortho substantial, irreversible lost profits, price erosion, loss of market share, lost jobs, and loss of goodwill. The Federal Circuit has recognized that such injuries may constitute irreparable harms. See, e.g., Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008).

Price erosion is most likely to occur in cases like this one, in which no generic competitors have yet entered the marketplace, placing the patentee in an exclusive position. This Court rejects Barr's contention that money damages could adequately redress any injury to Ortho. As the Federal Circuit explained in Polymer Techs. v. Bridwell, 103 F.3d 970, 975 (Fed. Cir. 1996):

> Competitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction. Customers may have established relationships with infringers. The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat. Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.

Barr contends that Ortho's asserted injuries are "all merely different ways of saying that Ortho will lose money due to Barr's competitive product," and that such money damages are all calculable and redressable. (Def.'s Opp. Br. 27.) This Court does not agree: Ortho has

persuaded this Court that allowing a generic competitor to enter the marketplace will damage its position in the TCL market in a way that cannot be undone, and that such damage will not be readily and accurately quantified, such that it may be fully redressed by money damages. This factor weighs in favor of granting the preliminary injunction.

III. Plaintiff has demonstrated that the balance of hardships and the public interest weigh in favor of granting the preliminary injunction.

Barr argues that it is Barr, rather than Ortho, that faces real harm at this juncture, because it stands to "lose forever the first-mover advantage it has earned." (Def.'s Opp. Br. 30.) Barr raises the possibility that a grant of a preliminary injunction would permit Ortho to offer an authorized generic. This argument has some merit, but the scenario Barr raises would be better addressed by granting the injunction, but simultaneously conditioning it on Ortho's agreement to refrain from offering a generic product for sale during the pendency of the injunction. This is a far better way to balance the hardships.

Barr also argues that, by launching its product, it has triggered the 180-day exclusivity period it earned by being the first ANDA filer, and that this period will run whether or not it is enjoined. Yet this hardship is solely of Barr's own making, and could have easily been avoided by not launching its generic product. Because Barr has caused this hardship to itself, this Court will not weigh this hardship in Barr's favor. Rather, this Court finds that the hardship to Ortho from allowing a generic competitor into the marketplace far outweighs any hardship to Barr. Moreover, the best way to minimize the harm from granting the injunction is to proceed to trial on an expedited basis. The parties prepared to appear for trial one year ago and should be ready to do so again in short order.

Lastly, as to the public interest, the parties take the traditional positions of branded and generic pharmaceutical manufacturers. Ortho contends that the public interest favors the enforcement of valid patents, while Barr argues that the public interest favors the availability of low cost drugs. This Court finds, on this record, that the public interest favors encouraging investment in drug development by protecting and enforcing a valid pharmaceutical patent. Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1384 (Fed. Cir. 2006).

Ortho has asked this Court to Order Barr to recall all of the generic product that it has delivered for sale in the marketplace. Barr opposes a recall, contending that it would place an undue burden on it, and subject it to significant disruption and expense. This Court is not persuaded that a recall is not feasible. Moreover, this Court is satisfied that, unless a recall is Ordered, given the possibility that substantial amounts of generic product have entered the marketplace, preliminary injunctive relief would be inadequate and ineffective in ameliorating the harm to Ortho. Ortho's request for an Order of recall will be granted.

CONCLUSION

For the reasons stated above, this Court finds that all four factors in the preliminary injunction analysis weigh in favor of granting Ortho's motion for a preliminary injunction. Ortho has shown that it is likely to succeed on the merits at trial, that it is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in its favor, and that an injunction is in the public interest. Because all four factors weigh in favor of granting the injunction, Ortho's motion for a preliminary injunction, pursuant to 35 U.S.C. § 283, is granted, subject to the condition that Ortho agrees to refrain from offering a generic TCL product for sale during the pendency of the injunction. Barr must recall all generic product that it has delivered into the stream of commerce.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

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